EXHIBIT H

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO THE FOLLOWING CASES IN WAVE 2 OF MDL 200:	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
Tamara Carter, et al. v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-01661	
Sandra Childress, et al. v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-01564	PAUL J. MICHAELS, M.D.
Marion Chrysler v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-02060	JUNE 18, 2016
Melissa Sanders, et al. v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-01562	
Ana Sierra, et al. v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-01819	
Toni Hernandez v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-02073	

Reported by:

Rebecca J. Callow, CSR, RPR, CRR

DEPOSITION OF PAUL J. MICHAELS, M.D.
THIS DOCUMENT RELATES TO CARTER
Austin, Texas
Saturday, June 18th, 2016
11:52 a.m.

Deposition of PAUL J. MICHAELS, M.D., pursuant to Notice held at the offices of Hissey Kientz, 9442 N. Capital of Texas Highway Building 1, First Floor Conference Room, Austin, Texas, before Rebecca J. Callow, Registered Merit Reporter, Certified Realtime Reporter, Registered Professional Reporter, and Notary Public in and for the State of Texas.

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PAUL J. MICHAELS, M.D.,
Called as a witness herein, having been first duly sworn by a Notary Public, was examined and testified as follows:
EXAMINATION
BY MR. SNOWDEN:
Q. Good morning, Dr. Michaels.
A. Good morning.
Q. I'm Andy Snowden. I represent Ethicon in the case that we're talking about today.
Is it your understanding that we're going to talk about the Tamara Carter case?
A. Yes.
(Exhibit 1 marked.)
BY MR. SNOWDEN:
Q. I'm going to hand you what's been marked as Exhibit 1. Would you please take a look at that and let me know if that contains your entire specific report regarding Tamara Carter.
(Document review.)
A. Yes.
BY MR. SNOWDEN:
Q. And does the case-specific report in Exhibit 1 contain all of your case-specific opinions

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for Tamara Carter?
A. Yes. The caveat to that is since this, I have reviewed her deposition, but it didn't really change any of my opinions in the case.
Q. Do you have any additions or corrections to make to your report before we get started?
A. Well, I guess, the only thing I would say is after seeing her deposition, you know, it seems like her -- the number of pregnancies and deliveries changed from one place to another.
So I guess the only thing I would say is that she's had multiple pregnancies that resulted in multiple deliveries rather than saying four and two and one. Just because it seems like that was kind of all over the place.
Q. Okay. Does that have any effect on your, any of your opinions in this case?
A. No.
Q. When were you first asked to work on the Tamara Carter case?
A. I don't have my -- oh, you know what?
It would have been, I would say, likely in March of this year.
Q. Okay. What were you asked to do?

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A. I was asked to review her slide from her mesh excision and review her medical records and basically write an expert report regarding my opinions with respect to both of those.
Q. How much time have you spent working on Ms. Carter's case to date?
A. I don't have that in hard copy with me. I would say over 20 hours, but not over 30.
Q. How much of that time was spent looking at the pathology slide versus reviewing the other materials?
A. I don't know exact numbers. Maybe reviewing the slide, photographing it, everything, maybe when I add up all the time together, because I would look at it and then maybe come back to it again to photograph it another time and look at it a little more. Maybe over an hour, an hour-ish.
Q. And then the rest of that approximately 20 hours was spent reviewing medical records. Is that right?
A. Medical records and maybe reviewing literature regarding an issue I found in the case, writing the report. That took a significant amount of time. Discussions about the case. That would be

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mainly it.
Q. Okay. Did you do anything to prepare for your case-specific deposition?
A. I reviewed her deposition.
I reviewed my report again.
I reviewed some of the medical records again. Just very briefly went through the medical records, not to the extent I did the first time.
I reviewed the defense pathology expert report, and that was mainly it.
Q. Are you relying on any of the articles written by Dr. Iakovlev or any of his expert reports or depositions for any of your opinions in this case?
A. Yes.
Q. Okay. Which ones?
A. I would have to go through this list.
(Document review.)
A. I don't have all of the authors listed out. There's some that he's listed as an author but it's not the first few. But basically, his article about degradation of the mesh.
BY MR. SNOWDEN:
Q. Do you recall what year that was published?

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A. I don't.
Q. Was that -- I'll strike that.
And I think you have an article -- a literature reference, number 6. It's Bendavid, "A mechanism of mesh-related post-herniorrhaphy neuralgia."
I believe that's a -- is it your understanding that's a Dr. Iakovlev article as well?
A. Yes, but there --
Sorry. I understood your question to say with regards to my opinions in this case, and that article dealt with neuroproliferation.
Q. Okay.
A. And there wasn't any of that in this -- the small amount of mesh that was in the slide.
Q. Okay. Are you relying on any deposition testimony for your opinions in Ms. Tamara Carter's case? Let me ask a better question. Sorry.
Are you relying on any of Dr. Iakovlev's deposition testimony for any of your case-specific opinions here?
A. No.
Q. Are you relying on any of his expert reports in other litigation for your case-specific

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opinions in this case?
A. No.
Q. When did you first review Dr. Iakovlev's degradation article?
A. A while ago. I don't -- I couldn't tell you. Relatively early on in this -- in my involvement with these cases.
Q. So that would have been prior to issuing this report in this case. Is that right?
A. Yes.
Q. Is that where the term "bark," in your opinion, comes from?
A. From where?
Q. Does it come from Dr. Iakovlev's article that you mentioned?
A. I've seen it referenced in a few different places. I don't know if that's the only place, that that's the origin of it.
Q. Okay. Do you recall any of those other places where "bark" is referenced?
A. I don't remember what Ethicon scientists called it. I know they addressed it as well in the '80s or something when I reviewed those -- their own documentation regarding their studies.

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But I found that that's not uncommon in pathology where people refer to the same thing by different names, and I assume that that's -- they were all talking about -- not assume, but they were all talking about the same thing, based on their diagrams and pictures.
Q. Are you relying on any other medical literature in this case that describes a -- and I'm using "bark" in quotes -- layer under the light microscope?
A. I don't remember if -- if it's been used in other places.
Q. In this case, did you receive a gross specimen?
A. No.
Q. And was your review -- and strike that.
How many specimens did you receive in this case?
A. I just received one slide.
Q. Okay. And was that from the September 27th, 2012, excision surgery?
A. Yes.
Q. Let's go to -- well, how did you make sure that it was from that surgery when you first

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reviewed the slide?
A. The date on the slide, I think it was 2012, and it correlated with the sheet that I received from the lab.
Q. Other than review under the light microscope and the use of polarized light microscopy, did you do any other testing of any specimen for Ms. Carter?
A. No.
Q. If you could, turn to page 9 of your report. You have, it looks like, an HNE picture at the bottom. Do you see that in your figures?
A. Yes.
Q. Can you describe what we're seeing in that figure? And is this -- strike that.
Is this Figure 1? Because it's a little confusing because the headings are cut off from the page.
A. Oh, yes. And it's Figure 1.
Q. So Figure 1 on page 9, please tell us what's depicted.
A. So that is, I would say, a medium magnification view of a fragment of the mesh where you can see the refractile polypropylene surrounded

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by dense fibrous tissue with chronic inflammation.
Q. What kind of chronic inflammation is present?
A. I don't know what you mean by what type of -- chronic inflammation: That's what it is.
Q. Okay. What type of cells do you consider in that -- being the chronic inflammation present here?
A. I would say mostly lymphocytes, although there are likely some macrophages as well.
Q. Are there any other foreign-body giant cells present?
A. This magnification, I can't really tell.
Q. Do you recall finding foreign-body giant cells in Ms. Carter's specimen?
A. Yes.
Q. Do you know how many you found?
A. I didn't count them.
Q. In Figure 1, could you ...
(Pause in proceedings.)
BY MR. SNOWDEN:
Q. Could you, using that red pen, mark the areas of chronic inflammation on Figure 1?
A. By an arrow or circling, or how should I do

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it?
Q. Why don't you circle the areas of chronic inflammation.
MR. AYLSTOCK: And, Doctor, you'll want to put something under that because that marker will bleed through.
BY MR. SNOWDEN:
Q. Here. Why don't we use the red pen.
(Witness complies.)
(Pause in proceedings.)
A. I would say I circled the main areas that I can see at this magnification.
BY MR. SNOWDEN:
Q. Okay. Did you find any -- well, is there any acute inflammation in Figure 1?
(Document review.)
A. I don't think I saw any acute inflammation in this specimen at all.
So at this magnification it would be hard to ascertain the difference between them, so I would say likely not.
BY MR. SNOWDEN:
Q. Okay. In your practice, do you typically grade the degree of inflammation in a specimen?

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A. Could you repeat that?
Q. Yeah.
In your practice, do you grade the degree of inflammation when it's present?
A. In some types of specimens, yes.
Q. Did you do that in this specimen?
A. No. This isn't one of the types that I grade inflammation in.
Q. Which types do you grade inflammation in?
A. Liver biopsies for hepatitis, you -- there's a grading scale for inflammation.
Heart biopsies for acute allograft rejection we grade inflammation.
Same with kidney allograft rejection we grade inflammation.
You grade some inflammation in some types of non-neoplastic diseases of the colon, like when you're evaluating for inflammatory bowel disease like ulcerative colitis and Crohn's disease.
Same with celiac disease. In the small intestine, we grade the types of inflammation and the degree.
I would say those would be the main specimens where, in the pathology report, it would

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be important to issue some sort of statement regarding the degree or severity of the inflammation.
Q. Is it important, then, when you're looking at a mesh removal to know the degree of inflammation?
A. Not as far as a grading system because there's really not one that exists, to my knowledge, that's used.
Q. Is there any way you differentiate between what -- for instance, what you see in Ms. Carter's case and other cases when it comes to degrees of inflammation?
A. Just by looking at pictures, if I were to compare pictures, I would say one has a more significant degree of inflammation than the other.
This is certainly -- I would not consider this minimal or slight, because that would just indicate just -- from a general pathologist's standpoint, that kind of terminology would indicate a very few scattered lymphocytes or macrophages or plasma cells that are not being clustered.
These are large groups of lymphocytes that are, you know, adjacent to the mesh within the

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fibrous tissue, so I wouldn't come up with a term to grade them. I would just take a picture of it and comment that there was chronic inflammation there.
Q. For all of your figures -- and you have six of them -- are you able to point to any nerve receptors?
A. Nerve receptors?
Q. Yes.
A. No.
Q. Do you have any nerves pictured in your photos?
A. There are probably nerves on Figure 3, but it's a really low magnification view, and they are not within the fibrosis of the mesh, so I didn't comment on them.
Q. Let's go to Figure 3.
A. Okay.
Q. You said there are probably some -- and just tell me if I'm wrong here.
There are probably some nerves, but they're not in the fibrosis of the mesh in Figure 3.
Where does the fibrosis of the mesh stop in Figure 3?
A. Do you want me to draw it?

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Q. Yes. If you want to draw a line.
A. I would say the scar plate is pretty -- this is actually a really good case, because you can clearly see this rounded encapsulating fibrosis which is described in the literature with regards to these. So ...
Q. So you've drawn an oval around the area of fibrosis.
A. Yeah. I may -- there may be a little bit that extends up to here, but the actual sclerotic -- where you can see the clefting of the fibrosis is pretty clear around here and extends a little up there.
Q. How do you differentiate between clefting of fibrosis versus the presence of loose connective tissue?
A. Pathology residency.
Clefting is a microscopic finding that you look at and you say there are clefts between the tissue. It's not really -- you don't see that in normal, loose -- loose fibrosis tissue.
Q. Are there any books we can look at that would show us that?
A. Probably any general pathology book. Not

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that I brought with me.
Q. Any that you can recall?
A. Probably Robbins Patho -- or Robbins & Cotran, Enzinger and Weiss, Goldblum's book. Any soft tissue book, I'm sure, describes the presence of clefts within fibrosis tissue, both in a non-neoplastic and neoplastic setting.
Q. Would something like that be found in gynecologic pathology texts?
A. Yeah. I would think so.
Q. Are there -- are there authoritative gynecologic pathology texts?
A. There are several gynecologic pathology texts?
Q. Okay. Are there any that you have used in the past or continue to use?
A. There are several.
Q. Any in particular?
A. Dr. Young's book.
Christopher Crum's book. Those are the two main ones.
Some people use Robboy. I don't tend to use that one very much. Olivi and Nucci have a book. That's a good book.

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Q. So far you've only named people at Harvard. Anyone else?
A. Well, if you know anything about books, you know that they have chapters written by people that aren't at Harvard.
Q. Okay. Blaustein's "Pathology of the Female" --
A. I don't -- I've never liked that book.
Q. Okay. Why not?
A. I don't like the way it's written. It has a lot of not useless information, but it just seems -- it's not very helpful from a pathologist's standpoint. Most people that I've worked with don't use that very much.
I mean, it's obviously a big textbook, but I personally -- you're asking about what I use. I don't use that.
So WHO for, you know, ovary and cervix and uterus. That's the international book. So those would be the main ones.
Q. Okay.
A. The Fascicles. The AFIP Fascicles.
Q. Are those books that you've mentioned typically written by leaders in the field -- sorry.

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Let me start over.
Are the chapters in those books typically written by leaders in the field?
A. No. I wouldn't say so. Not typically.
I mean, they're written by people that -- the editors who are the leaders in the field will say, "Hey, do you want to write a chapter on such-and-such?"
"Okay. I'll write a chapter on such-and-such."
And then it will be reviewed and edited by the leaders in the field, but not taking anything away from the people that have written chapters whatsoever.
But I wouldn't say that because someone has a chapter in a book it anoints them as a leader in the field.
Q. If you take a look at Figure 2 -- actually, before we move to Figure 2, where in the body did Figure 1 come from?
A. I think it came from the posterior vaginal wall, to my recollection. That's what it was reported to have come from.
Q. All right. Do you know where in the

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posterior vaginal wall?
A. I couldn't point to a location.
Q. What significance to your opinion in this case is the inflammation seen in Figure 1?
A. I guess I don't -- can you repeat that?
Q. I'll ask a better question.
Do you place any significance to your finding of chronic inflammation?
A. Well, I evaluate all of the findings together. So it's not just that there is chronic inflammation, it's the degree of chronic inflammation, the location of the chronic inflammation, exquisitely surrounding the mesh. Its location within the dense fibrosis that's surrounding the mesh.
So it's more than just, for me, seeing that there's chronic inflammation, it's knowing where it is in the biopsy and what it's intimately associated with, which in this case is the mesh, which shows that there is significant inflammatory reaction to the mesh in this patient.
Q. Okay. Earlier you told me you don't typically label the degree of inflammation and you just told me the degree of inflammation is important

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to your opinion.
A. No. I don't grade the degree. So I don't say -- you were asking initially about grading, and I said that I don't grade the degree of inflammation.
But noticing the quantity without placing a grade on it is something that you do when you compare from one to another.
Q. Okay. The quantity of inflammation in Ms. Tamara Carter's case, how does that compare to other cases?
A. I would have to see the picture of it to show you how it compares.
Q. Okay. Is this -- is this a slight reaction, a moderate reaction, a marked reaction, or you just wouldn't place a grade on it?
MR. CURTIS: Object to the form of the question.
A. I would say it's somewhat moderate based on this picture.
BY MR. SNOWDEN:
Q. Okay. And that's -- based on Figure 1 that's moderate inflammation.
A. Well, I mean, again, like I said, I'm

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not -- I'm not grading it.
So I'm saying it's -- you know, it's a good amount of -- it's not slight, it's not all over the tissue. And you're not going to force me to grade it when I'm telling you that I don't grade them, so ...
Q. Okay. So what significance does the degree of inflammation have on your opinion in this case?
MR. CURTIS: I know it was not intentional, but you've cut him off a couple of times. Would you please wait until the doctor finishes his answer.
MR. SNOWDEN: Sure.
THE WITNESS: Can you repeat that?
THE REPORTER: Yes.
(The record was read as requested:
"So what significance does the degree of inflammation have on your opinion in this case?")
MR. CURTIS: What was his answer?
Do you need to hear part of the answer that you gave?
THE WITNESS: No. That's fine.
A. I would say it supports my opinions.

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BY MR. SNOWDEN:
Q. How does it support your opinions?
A. Because it's showing that there is an inflammatory response to the mesh.
Q. Okay. Does it matter for your opinions -- strike that.
Does the degree of the inflammation matter for your opinions?
A. Well, if there was just one lymphocyte or two lymphocytes, I wouldn't comment on that. So the fact that I'm commenting on inflammation means that I'm considering it pathologic in this case, which I do.
Q. And at what point do you consider it pathologic?
A. There's no way for me to really count the number of lymphocytes as we sit here and tell you how many wouldn't be.
I can tell you from this tissue removed from this client, Ms. Carter, that this is significant, and that's what I would say and that's what I did say in here.
Q. But in this case you're not using a grading system. Right?

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A. Right.
We don't -- I don't use -- none of us use grading systems for --
Q. And --
A. Don't. Stop cutting me off.
Q. I -- actually, I haven't said anything.
A. Yeah. You were starting to talk.
So, as I said, we don't use grading systems. I'm not doing a study. So in studies they may say grade 0, 1, 2, 3. We don't do that when evaluating these types of specimens, we would just comment on whether there's inflammation present. And in this case I took pictures of it to demonstrate that morphologically.
Q. So do we just have to take your word for what level it becomes significant?
MR. CURTIS: Object to the form of the question.
A. I took pictures. So no. You don't have to take my word for it, because I took pictures.
So, by definition, it's not just my word, it's an image demonstrating what I've described.
///

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BY MR. SNOWDEN:
Q. Okay. Is it your testimony that it's not common in the field of pathology to rate or put a degree on inflammation?
A. Okay. So we can go over this again, but there are certain locations in the body and certain diseases where you do grade inflammation routinely.
Now, when you're looking at a vaginal mesh erosion that is taken out with fibrous tissue, then we don't typically grade them with a numerical score.
In this case, what I do is I described that there was chronic inflammation. And I took pictures to demonstrate the chronic inflammation so that at trial when I'm describing this, I can show the number of inflammatory cells and how they're surrounding the mesh and present within this scar fibrosis tissue.
Q. So how many inflammatory cells did you count?
A. I didn't count them. I wouldn't have. That's not a standard.
Q. That's part of your answer, though. We'll move on.

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MR. CURTIS: Just a minute. Just a minute.
MR. THOMAS: Let's get an even keel here.
MR. CURTIS: Refrain from making remarks that are not a question. It's just not appropriate for you to editorialize about the answers that you don't like, and we're not going to do that.
MR. SNOWDEN: And I'd ask that that go both ways.
MR. CURTIS: But it starts with you. Because you're not going to antagonize this witness.
MR. SNOWDEN: You're wasting my time.
MR. CURTIS: Just change your attitude. You came in here with some burr up your ass. I don't know what it is, but settle down and ask your questions --
MR. THOMAS: Let's go off the record.
MR. SNOWDEN: Let's go off the record.
(Discussion off the record.)
BY MR. SNOWDEN:
Q. All right. Dr. Michaels, if you could turn to Figure 2 of your report.

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Could you please tell us what we see here in this photo?
A. So in this photo there are mesh spaces towards the left of the photo with a little bit of mesh that's still in there on the bottom left.
And there's -- excuse me -- chronic inflammation with lymphocytes and macrophages, and there's some multinucleated foreign-body giant cells, there's some dilated blood vessels, and there are areas of fibrosis at the upper right and lower right periphery of the figure.
Q. Okay. The figure legend says, "Granulomatous tissue reaction associated with adjacent mesh filaments."
Do you see that?
A. Yes.
Q. What makes this granulomatous?
A. The fact that there are foreign body-type giant cells and histiocytes.
Q. What significance, if any, does the presence of granulomatous tissue have on your opinion in this case?
A. Well, it's showing that there's a reaction to the foreign material present within the specimen.

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Q. Do you grade the degree of granulomatous inflammation?
A. No.
Q. Anything else of significance in Figure 2?
A. I think I just described basically the whole figure, so in that -- I guess, in this particular objective, that would be what I would describe from it.
Q. Turn to -- well, before we do that, did you measure the thickness of the granulomatous inflammation in this case?
A. No. I didn't quantify or measure the thickness of the granulomatous inflammation.
Q. Does that have any impact on your opinions in this case, the thickness of the granulomatous inflammation?
A. No.
Q. Does it just matter that it's there?
A. That it's there and that it's quite visible, and the location of it.
Q. Okay. Let's go to Figure 3. What do we see in this photomicrograph?
A. So towards the bottom of the tissue piece there is a portion of mesh that's surrounded by

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fibrosis and has fibrosis between the filaments, and there's associated inflammation around those individual filaments.
And then the upper part of the figure shows more -- shows the adjacent stroma within the specimen that has -- you can see the obvious -- well, you can see blood vessels in the upper part with some of the more edematous -- I should say not edematous, but loosely -- loose stroma.
Q. Did you -- I think earlier we talked about -- you drew a circle on the figure and you said this was the encapsulated scar. Did you measure the thickness of the encapsulated scar in this case?
A. No. I didn't measure the thickness of the encapsulating scar in this case.
Q. Does that have any impact on your opinions?
A. No. It doesn't have an impact on my opinions.
Q. Why not?
A. Because it matters that it's there, not the size of it.
Q. Did you measure the distance from the mesh to -- well, let me start over.

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Outside of the circled area on Figure 3 that you've put on the exhibit, is the tissue -- would you call it normal?
A. It appears unremarkable --
Q. Okay.
A. -- from this magnification.
Q. All right. Did you measure the distance from the mesh fibers to unremarkable tissue in this case?
A. No.
Q. Does it matter to your opinions?
A. No.
Q. Why not?
A. Because what is in the mesh is abnormal. So it's not like they need to excise -- it's not like a tumor, that it's malignant and you have to measure how close the tumor is to the resected margin.
There's no need to measure anything. Just because there's normal tissue adjacent to the mesh means nothing from this -- the distance.
Q. Figure 4 in your report: Is this a higher magnification of the bottom portion from Figure 3?
A. Yes.

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Q. What are we looking at in Figure 4?
A. We are looking at the fibrosis between the two areas of mesh filaments, and we're also seeing the clefting of the fibrosis tissue, which you just see when you have sclerotic scar tissue basically, or fibrous tissue.
And then you can also see that each of those mesh filaments is surrounded by a chronic inflammatory response. And then we know from the prior one -- one of the prior figures that there is evidence of a granulomatous response with the foreign-type giant cells.
Q. Did you -- well ...
And then Figure 5: Is that an even higher magnification of the middle portion of Figure 4?
A. Yes.
Q. Do you have an opinion in this case regarding whether Ms. Carter's mesh contracted in her body?
A. Yes. I would say that based on these findings it appears that it -- it would have.
Q. And which findings specifically are you referring to?

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A. The encapsulating fibrosis would probably be -- I would say the most suggestive finding to correlate histologically at least, because that's what you typically see in any aspect of the body when you have scar tissue. When it's surrounding a structure, that's when you have that kind of shrinkage or contracture.
So I would say that that would be the histological correlate to a contracture.
Q. And what -- what's the basis for your opinion that the presence of fibrosis is a histological correlate for contracture?
A. My entire, I guess, experience as a pathologist, that that's -- and my reading. That's what you see with contractures is, you see dense fibrosis. You see a fibrous scar.
Whether it's a contracture in someone's hand or vaginal region or something in the abdomen, that's -- the histologic correlate is usually dense hyalinized cellular fibrosis.
Q. Is that found in any medical literature anywhere?
A. Yeah. Everywhere.
Q. Are you relying on any medical literature

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for that opinion?
A. My kind of career of reading medical literature. It's not like it's only been described in one location. I'd say "Oh, yeah. So-and-so mentioned it in 1995."
It's just kind of a general -- it's a general. It's general knowledge. Pathology knowledge.
Q. Did you measure the pore space in Ms. Carter's specimen?
A. No.
Q. Do you know whether you saw a pore in the tissue specimen?
A. Well, I didn't examine the gross tissue specimen.
Q. Are we looking at a pore in Figure 4?
A. That's the space between it. Correct.
Q. And so --
A. This is -- this would be deformed, technically. I mean, it's a different area.
This whole area is sort of deformed because it shouldn't just have -- you have clusters of filaments here, so it's kind of indicative of the fact that it's sort of deformed.

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Q. Okay. Take me through next -- I don't understand why --
Why do the clusters of fibers mean it's deformed?
A. Well, you can see that this is -- it's not uniform. So you have like four -- on the right you have four filaments spaces, where on the left you have six and they're at different spacing.
So normally, when you would have the mesh prior to implantation, everything would be uniformly spaced. But in here, you can see, based on its incorporation into the tissue, that it's not. So I'm using that to say that it's, by definition, not the same form, so it's deformed.
Q. Have you sectioned the pristine mesh and looked at it under a microscope?
A. Like unremarkable mesh?
Q. No. Pristine mesh out of the box.
A. No.
Q. Have you ever seen a TVT out of the box?
A. Under the microscope?
Q. Under the microscope or just in person. Have you had one in your hands?
A. Yes.

Q. When was that?
A. In medical school or probably towards the end of medical school.
Q. Have you ever had a Prolift in your hands?
A. I don't recall if I've ever had a non-used Prolift in my hands.
Q. Okay. If I asked you to -- and I'm not asking at this point, but would you be able to draw the structure of a Prolift?
MR. CURTIS: Object to the form of the question.
MR. AYLSTOCK: And I would also say this is -- I don't know, this is general questioning.
MR. CURTIS: Yeah.
MR. AYLSTOCK: We're really far afield of Ms. Carter and you're -- and his case-specific opinions in this case. So we provided ample opportunity for general questioning, that deposition is closed.
MR. SNOWDEN: And I'll have to respectfully disagree with you. Dr. Michaels just testified that as part of this case he can tell it's deformed based on the structure, and I'm trying to

figure out what the basis for that opinion is.
BY MR. SNOWDEN:
Q. So, Doctor, if I asked you to -- and I'm not right this second -- would you be able to draw the filament structure of a Prolift?
MR. CURTIS: We object to the form of the question. And I can tell you that we're not going to engage in any drawing of the --
MR. SNOWDEN: I haven't asked him to.
MR. AYLSTOCK: And are you talking about the outline of the mesh or --
THE WITNESS: Yeah. I don't understand.
MR. AYLSTOCK: The whole thing is confusing.
BY MR. SNOWDEN:
Q. If I asked you to draw a pore with the outlining mesh filaments, could you do it?
MR. CURTIS: I continue to object to the form of the question.
And I think Mr. Aylstock is right: That that's far afield from his testimony that this particular Figure 4 depicts deformed mesh in this particular patient.

BY MR. SNOWDEN:
Q. You can answer.
A. Yeah. It's like a crisscross.
So, I mean, I'm not a good drawer, but I've seen it; I've held it in my hands, as I've already testified, but -- and I've seen the difference between anterior and posterior in the Total Prolift, so I -- I could -- you know, I know what that looks like as well, so ...
Q. And this is my last question on this.
How many filaments surround a Prolift pore?
A. I'm not --
MR. CURTIS: I object to the form of the question.
Go ahead.
A. I would have to look at a picture of it.
BY MR. SNOWDEN:
Q. Did you do that before coming to your opinion that Figure 4 shows deformation of the mesh?
A. Could you repeat that?
Q. Yeah.
Did you look at a picture of a Prolift before coming to the opinion in Figure 4 that the

mesh was deformed?
A. Yes. I've seen the pictures before I came to that conclusion.
Q. Is there any blood vessels in Figure 4?
A. Yes.
Q. So would you agree this tissue is vascularized?
A. I would say the tissue in Figure 4 is vascularized.
Q. Is there any edema present in Figure 4?
A. It's hard to tell at this magnification for certain.
Q. Figure 4 captures every single mesh filament from Ms. Carter's body that you have reviewed. Correct?
A. I believe so.
Q. Okay. And so if we count them, it's a total of 10. Is that right?
A. Yes.
Q. Do you know whether this is a representative specimen?
MR. CURTIS: Objection. Representative of what?
///

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BY MR. SNOWDEN:
Q. Of the whole -- of Ms. Carter's specimen. Let me ask it again.
Do you know whether this is a representative specimen of the whole of Ms. Carter's excised mesh?
A. I would -- well, it's my opinion, just based on how your body reacts to foreign material, that this would be representative of what's not sampled that's in her body.
Q. So the inflammation we see here in the fibrosis, we see here you expect that to be equivalent or similar throughout the rest of the specimen.
A. I would say that it would be similar, although changes obviously occur if it's -- because in this area, we don't actually have it eroding through the mucosa.
So when it's eroding through the mucosa, I would imagine there would be more acute inflammation or hemorrhage or edema, depending on if it's located near -- you know, if there's mesh near the -- some of her mesh has migrated. It's near the urethra, it may be involving smooth muscle or it

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could be involving skeletal muscle, which could cause, again, a slightly different response.
But, generally, I would say that it would be similar, the basis of the inflammatory response.
Q. You brought up a good point.
You didn't see the erosion site in this case, did you?
A. Correct. This was the only slide I have.
Q. So you didn't see any mucosa.
A. I don't remember if there was mucosa on this. It wasn't -- let me look. I thought that there was, it just wasn't at the mesh.
Yeah. There's squamous mucosa.
Q. And did you -- did you see mesh near the squamous mucosa in this?
A. Well, I mean, it depends on how you define "near."
Q. How do you define it?
A. Well, it's within a few millimeters of the mucosa. That's certainly closer than if it was 5 centimeters away. You would say that that was relatively near compared to something farther.
So -- but it wasn't -- in this

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particular section, it wasn't in continuity with the epithelium.
Q. Do you recall there being five portions of tissue on the slide you reviewed in this case?
A. Yes.
Q. Is there any reason you didn't take photographs of the other four?
A. They didn't have mesh, and the report was on the reaction to the mesh.
Q. Is the -- did you remark at all about the tissue in the other four pieces in your report?
A. Yes.
Q. Where is that?
A. It's under the microscopic findings.
Q. All right. So what's your opinion regarding what you saw in those other four pieces?
A. Well, as I say, I say, "The histologic section show numerous fragments of tissue, some of which are lined by reactive and acanthotic squamous mucosa with underlying stromal edema, and others that show fibromuscular and fibroneural tissue."
And then I go on to say, "In one fragment ..." and I describe the mesh.
Q. Okay. Was there anything significant about

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those other four pieces?
A. I didn't think that there was anything other than what I described that showed significant pathologic change other than the stromal edema that's underneath the mucosa.
Q. Figure 4: Do we see any nerves in this clear micrograph?
A. It's hard to tell if there are any nerves at this magnification.
If they are, they would be small, and I didn't think that they were within that fibrosis of the -- between the mesh.
Q. Is it fair to say you didn't find any nerves that you would consider were entrapped in the scar tissue?
A. Yes. I agree with that.
Q. Okay. Is it fair to say you didn't find any deformed nerves in this case?
A. Yes. And I didn't have an S100, which limited my ability to find any. But based on HNE alone, I did not see any deformed nerves in this case.
Q. So fair to say, then, there are no traumatic neuromas in this specimen that you

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reviewed?
A. I didn't notice any traumatic neuromas in the specimen.
Q. Would that have jumped out at you? A traumatic neuroma.
A. It depends. It should.
Q. What do we see in Figure 5?
A. Well, again, we see prominent hypocellular and hyalinized fibrosis that's extending between these mesh filaments that I have with arrows. And at the arrows you can also see a chronic inflammatory and foreign body response.
Q. We also see blood vessels in Figure 5. Is that right?
A. There are tiny compressed blood vessels.
Q. So you'd agree this tissue is vascularized.
A. Well, there are vessels in it, but they are compressed and I don't see red blood cells within them. It's certainly not necrotic. It's not -- it doesn't look like there's no vascular supply getting to it.
Q. Are those red blood cells in the granulomatous tissue described in Figure 2, and are actually pictured in Figure 5? That's the left

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portion of the picture.
A. Yeah. At the edge.
Q. What are the tiny -- other than the chronic inflammation, what are the tiny purple dots in Figure 5?
A. They're a variety of cells.
Q. Did you look at these to determine what type of cells these were?
A. Well, they're fibroblasts, and they're endothelial cells, and they're perimyocytes associated with the vessels. There are probably some mast cells that you often see in stromal tissue.
Q. Anything else?
A. Nothing striking that jumped out at me.
Q. We've gone through five of your figures and you've described your findings in them. Can you tell us what impact this is having on Ms. Carter?
MR. CURTIS: Object to the form of the question.
(Document review.)
A. So I would say that based on the features that I identified histologically that they would be a morphologic explanation for her symptoms

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dyspareunia, pain to palpation. And then extrapolating based on, as we talked about, knowing that these findings would be representative of other areas of her mesh that were not removed.
Urethral fistula formation, recurrent urinary tract infections, and a recurrent stress urinary incontinence. Knowing that this was in an area away from her bladder, but knowing that the same mesh substance was in other areas, I would say you could extrapolate from that, which we do as pathologists all the time when we only see a small bit of tissue but have to make an evaluation based on a larger specimen.
BY MR. SNOWDEN:
Q. In answering my question, I notice you reviewed a portion of your report.
Were you looking for the clinical symptoms that Ms. Carter experienced? Was that part of what you had reviewed?
A. No. I was reviewing what I reported and the actual time of when this mesh was taken out, and what I had summarized.
Because there's a lot of information in these cases, and before I give you a thoughtful

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answer that I want to be accurate and precise, I wanted to review to make sure that what I'm saying are her symptoms or her -- what impact this tissue had is accurate.
Q. Had you looked solely at the tissue without any clinical history in this case, could you have told us those clinical symptoms?
MR. CURTIS: Object to the form of the question.
A. I didn't do that. That's not what I was asked to do.
BY MR. SNOWDEN:
Q. Okay.
A. So I can't really postulate what I could have done without that scenario. I wasn't in that scenario.
Q. But are you able to look at any of these figures in your report and tell me what impact this tissue reaction is having, was having, on Ms. Carter's pain?
MR. CURTIS: Object to the form of the question.
A. Well, I don't operate in a vacuum, so I can't just look at one picture and tell you

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everything about the patient.
I, and other pathologists and other physicians, have to take everything into account and put them together and rule out other etiologies of pain. And there are tons of etiologies of pain you can identify microscopically, and I didn't find any of them in this material.
So I can't just look at one picture in a case like this and dictate what kind of symptoms or signs she was showing.
BY MR. SNOWDEN:
Q. How about all the pictures? Could you look at all the pictures and say that?
MR. CURTIS: Object to the form of the question.
BY MR. SNOWDEN:
Q. Let me reask the question.
If you look at all the pictures together, would you be able to do that?
MR. CURTIS: Object to the form of the question.
A. Again, I told you regarding any of these I'm not operating in a vacuum. I wasn't just asked to look at the histology and write a report about

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what my findings were.
I was asked to look at the histology in conjunction with the medical records and issue a report basically saying what I felt if I felt like these correlated, which I do.
And part of that was evaluating the tissue and making sure there weren't other findings. And there are several that can be found in any given case that could have basically said that these other finding, in addition to the mesh, this other finding actually could have equally have produced pain, and I didn't see any evidence of that in this case.
BY MR. SNOWDEN:
Q. How did the reaction to the mesh -- how does it correlate with the clinical symptoms in this case?
A. Well, the inflammation and the scarring would lead to basically deformation and an inflammatory reaction associated with the actual filaments that are present. And the contracture, based on the fibrosis, would lead to an anatomic, basically, malfunction, if you will, of the general area and could lead to pain. Obviously, the extrusion, because when it's contracting and there's

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inflammation, it's going to move within the tissue, and, depending on the location, can lead to urinary dysfunction.
Q. Did this mesh that we're looking at in these five figures lead to urinary dysfunction?
A. Well, this particular mesh was -- again, it was taken from posteriorly, so it wasn't in that area.
So as we've already -- as I've already mentioned, I think you can take -- well, it's my opinion that you can take these inflammatory processes that are occurring in a mesh that is uniform throughout its actual product.
It's not as if when you have a mesh product they coat part of it in one polymer and another part in something else and then they add other coating to another part. It's uniform.
So the tissue reaction you see in a small amount would correlate and you can extrapolate to other parts of the tissue, assuming that it's in other parts of the body, which it is.
It's not just in this posterior vaginal wall, it's in other -- this is just -- this isn't representative of how much tissue -- how much

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mesh she has in her body.
Q. Did you review a specimen taken from Ms. Carter's anterior vaginal wall?
A. No. I think we've already gone over that.
This is the one specimen that I have where there are five fragments of the tissue that are on the slide, and it was taken, reportedly, from the posterior vaginal wall.
Q. Which device are we looking at in these figures?
A. The Prolift.
Q. What aspect of the Prolift device led to the changes -- the tissue changes we're looking at in these figures?
MR. CURTIS: Object to the form of the question.
A. I don't know what you mean.
BY MR. SNOWDEN:
Q. What about the Prolift led to these tissue changes, if you know?
A. I don't know what you're talking about. I don't understand that question.
Q. How did the Prolift cause these tissue changes which you're correlating with Ms. Carter's

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symptomatology in this case?
A. Because it's a synthetic foreign body.
I don't know what you're getting at. I don't understand.
Q. I'm asking -- I'm just asking for your opinion on what aspect of the Prolift device led to the tissue changes you're correlating with Ms. Carter's symptomatology?
MR. CURTIS: Object to the form of the question.
A. The polypropylene mesh and its characteristics.
BY MR. SNOWDEN:
Q. Okay. Which characteristics led to the tissue changes we see here?
A. I guess I don't understand the question.
Q. Do you have an opinion as to the specific elements of the Prolift device that led to the tissue changes we see in Ms. Carter's case?
MR. CURTIS: Object to the form of the question.
THE WITNESS: Can you repeat the last question?
THE REPORTER: Yes.

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(The record was read as requested:
"Do you have an opinion as to the specific elements of the Prolift device that led to the tissue changes we see in Ms. Carter's case?")
A. So, I guess, getting back -- I'm assuming this is a general question with regards to Prolift in general.
So, as we covered earlier, the heavy weight, the pore size, its location I would say in that anatomic region. All those together would correlate with the findings that we're seeing.
BY MR. SNOWDEN:
Q. Did you quantify the degree of contraction in Ms. Carter's case?
A. No. We don't quantify fibrosis in non-research settings in this location in the body.
Q. And I just want to make sure we're talking about the same thing.
I'm asking about the contraction of the mesh that I believe you've said you're opining occurred in this case. Did you quantify the degree of that contraction? Not the degree of the fibrosis.
A. Well, the contraction is secondary to the

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fibrosis. So when I'm talking pathologically about the contraction, I'm talking about what's causing it which is the fibrosis; and no, I didn't quantify any element of the contraction or fibrosis.
Q. Is there anything you could have done to measure or quantify the contraction in this case?
A. Not that I would have done that I'm aware of.
Q. Do you have an opinion in this case that Ms. Carter's mesh migrated?
A. Yes.
Q. Okay. And what's that opinion?
A. That it did.
Q. Okay. Where did it migrate from?
A. I can't give you exact anatomic locations. But the fact that it was eroded through the mucosa, by definition, is a migration.
So I don't -- I can't tell you that it took a 135-degree turn and went anterior, posterior -- anterolateral.
But it migrated from its normal location to coming out of the body. That's, by definition, migration.
Q. In your opinion -- strike that.

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Figure 5 you have in the legend "Prominent hypocellular and hyalinized fibrosis."
Do you see that?
A. Yes.
Q. What do you mean when you say "hyalinized"?
A. It means it's -- just for a layman's term, it's very pink and hypocellular. It's kind of -- when it's hyalinized, it has a glassy appearance.
Microscopically, it tends to be associated with these clefts, which you can see, which are these almost white tiger stripes that traverse horizontally.
That's hyalinization.
Q. Is the presence of hyalinized fibrosis significant to your opinion?
A. It's just evidence of dense fibrosis which you see in the setting of scars.
Q. Are you offering an opinion in this case that Ms. Carter's mesh degraded in vivo?
A. Yes.
Q. And what's the basis for that opinion?
A. My microscopic evaluation using polarization microscopy.
Q. Where did you get the idea to do that?

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A. From the literature and from Ethicon's own scientists who did the same thing.
Q. Which literature?
A. Well, I don't know the exact names of the studies. I know just a couple days ago I was rereviewing this and was, again, seeing the reports from Ethicon scientists that showed the same degradation.
And so when I first got involved, I was sort of pointed to that material because obviously, as a layperson in the medical community, I didn't have access to Ethicon's internal documents.
So those were provided to me, and then I did my own literature search and had other article -- peer-reviewed articles that I could review, like Dr. Iakovlev's article, and saw the findings, read about the findings. Read about the scanning electron microscopy, its correlation.
The prior medical literature, postulating about biofilm and that it's a protein polymer and not really a foreign synthetic material. And so after reading all of that and seeing them talking about polarization light microscopy, that's

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why I polarized these cases.
Q. What about the specimen in this case supports your opinion that the mesh degraded in vivo?
A. The outer polypropylene bark, or layer -- whichever you prefer to use -- is detached from the core, and it's also detached from the surrounding tissue and it's broken into numerous pieces.
Q. And is that what you have shown in Figure 6?
A. Yes.
Q. How did you -- well, let me start over.
Did you rule out artifacts of microtomy when determining that Figure 6 was degraded polypropylene?
A. Yes. It's my opinion from reviewing the literature that these findings are not from any sort of microtome or processing.
Q. And why is that?
A. From what I've read, that even without those -- in the pictures that I've seen, even without those processing features that you would still see the same findings without formalin fixation or cutting or anything. You still see

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cracking of that outer layer.
Q. And I think what you're referring to now are cracks with SEM photos. Is that right?
A. Um-hmm.
Q. Okay. And I want to focus specifically on what we're -- the specimen you reviewed -- well, let me start over.
Did you do any scanning electron microscopy on this specimen?
A. No.
Q. Did you do any transmission electron microscopy in this specimen?
A. No.
Q. Did you do any analytical chemistry tests on this specimen?
A. No.
Q. Okay. Your review of this specimen was limited to light and polarized light microscopy. Would you agree?
A. To the specimen, yes.
Q. And so the specimen we're talking about right now --
MR. SNOWDEN: I don't want to get into general opinions so that I draw a bunch of

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objections from you guys.
MR. CURTIS: Just ask your question.
MR. AYLSTOCK: Did I look like I was going to object? I'm sitting here minding my own business.
BY MR. SNOWDEN:
Q. From your review of the polarized light microscopy and light microscopy in this case, what is it that led you -- how did you rule out that this bark was not just an artifact of processing or microtomy?
MR. CURTIS: Object to the form of the question.
A. Because it doesn't have that appearance.
After years of looking at processing artifacts, it doesn't have that appearance. You don't see multiple little -- you wouldn't see this kind of architecture based on a microtome blade. It just makes -- it doesn't make any pathologic sense to me.
BY MR. SNOWDEN:
Q. Did you see any -- well, hold on one second. Sorry.
(Pause in proceedings.)

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BY MR. SNOWDEN:
Q. Other than Dr. Iakovlev's article and the Ethicon study that you referenced earlier, do you recall any other articles you're using for the basis of your degradation opinion?
And I'm specifically asking about with the use of light microscopy.
A. I can't recall.
Q. Do you recall in the article by Iakovlev, and others, that he -- one of the ways he asserts you can differentiate between non-degraded polypropylene and degraded polypropylene is the uptake of histologic stain?
MR. CURTIS: I don't know why this is not general. I mean, you're not asking him about his bases for the judgment he made in this case, you're talking about these --
MR. SNOWDEN: I absolutely am.
MR. CURTIS: You're talking about these articles and all this other stuff that was specifically covered. This same topic, this same author, this morning in the general.
BY MR. SNOWDEN:
Q. You can answer the question.

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MR. CURTIS: I object to the question.
A. Can you repeat the question?
MR. SNOWDEN: Can you repeat the question, please.
(The record was read as requested:
"Do you recall in the article by Iakovlev and others that he -- one of the ways he asserts you can differentiate between non-degraded polypropylene and degraded polypropylene is the uptake of histologic stain?")
A. I would have to see the article.
BY MR. SNOWDEN:
Q. You don't recall that?
A. I recall there being a mention about the stain, but I don't remember that it was specifically in regards to whether it's degraded or non-degraded. And before I answer any question about the article, I'd like to see the article.
Q. How do you determine, when you're looking under the microscope and coming to your opinions in a mesh case, that the fragments you see depicted in Figure 6 are degraded polypropylene rather than

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non-degraded polypropylene?
MR. CURTIS: I object to the form of the question.
A. Because it's morphologically similar to what's been described with respect to degraded polypropylene. And that's -- as a pathologist, that's the basis of my entire career is, you use literature and your own training and images of what is described as X, and then you see it yourself and you say, Based on my opinion and based on my knowledge of what is out there in the literature, what has been published, this is analogous to what is being described, and you come to your own conclusions.
So when I reviewed this particular case and looked at what we're seeing on Figure 6, my opinion is that that is degraded -- that's evidence of degraded polypropylene bark and not a processing or sectioning artifact.
BY MR. SNOWDEN:
Q. And what morphologic features are you using to come to that conclusion?
A. Well, as I said earlier, the fact that it's separated from the core.

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It's in multiple fragments.
It's also separated from the surrounding tissue.
You can't see that blue dye, because this is a polarized picture, so you can't see the actual blue dye.
But just based on those features, that's -- and correlating with the literature, that's how I came to that conclusion.
Q. Anything else? Any other morphologic similarities?
A. I think I described the main ones.
MR. CURTIS: Let's take a break, if this a convenient spot.
MR. SNOWDEN: I'd like to get through this line of questioning first, please.
THE WITNESS: I actually need to use the restroom.
MR. SNOWDEN: Okay.
MR. THOMAS: Let's take a break.
MR. SNOWDEN: Over my objection.
(Recess from 1:20 p.m. to 1:26 p.m.)
BY MR. SNOWDEN:
Q. Dr. Michaels, what, if any, clinical

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significance do you attribute to the degradation of Ms. Carter's specimen?
A. Well, the degradation of the polypropylene leads to increased inflammation which would then lead to increased fibrosis, which would correlate with her symptoms that I described in my report -- and signs in my report.
Q. That any -- and all symptoms attributed to the degradation layer?
A. Well, that's one aspect of the foreign body response. It increases the response and the inflammation which would then increase the fibrosis, so that's one element of it.
Q. Did you do a measurement of the degradation layer in this case?
A. No.
Q. Did you do any type of nerve density analysis in the specimen?
A. Well, I described earlier how there weren't any nerves that were entrapped.
So -- and I would only take into account what nerves were in the area of the mesh. So I didn't do any -- and even regardless, I would feel that that's something that would be more likely

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in the setting of a research study and similar to grading of inflammation in fibrosis that we've talked about. So I personally don't do that.
Q. Did you consult with a neuropathologist in this case?
A. No.
Q. Did you consult with any other pathologists regarding Ms. Carter's specimen?
MR. CURTIS: That was all covered this morning, his consultation with neuropathologists and other pathologists and even other experts.
MR. SNOWDEN: Regarding Ms. Carter or not?
MR. CURTIS: Regarding all six cases.
A. No, I did not.
BY MR. SNOWDEN:
Q. Have you spoken with any of the other -- well, strike that.
Have you spoken with anyone else other than counsel for the plaintiffs regarding Ms. Carter's case?
A. I don't believe so.
Q. Have you ever examined Ms. Carter?
A. No.

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Q. Other than --
A. I was going to say, not physically, just her tissue.
Q. Other than the one tissue slide you reviewed in this case, have you ever examined Ms. Carter?
A. No.
Q. Have you ever spoken with Ms. Carter?
A. No.
Q. Have you -- were you present during any of the surgical procedures Ms. Carter had?
A. No.
Q. Did you have an opportunity to view the mesh in vivo?
A. No.
Q. Did you have an opportunity -- strike that.
Have you read -- well, which depositions, if any, have you read regarding Ms. Carter's case?
A. Well, that's hard to answer, because within her case I have general opinions in this report that I had reviewed multiple depositions from Ethicon scientists and -- and then I've also, since this report, reviewed her -- her deposition testimony.

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But I don't recall reviewing any, like, treating physician testimony in this case or any other expert testimony in this case.
Q. And that's really what I'm after.
I'm after the case-specific materials relating to Ms. Carter and not depositions of Ethicon's employees or anything sort of in the general portion of your report.
If you turn actually to Exhibit -- well, it's toward the end of your report. You have a list, "Case-Specific Materials Reviewed." It's Exhibit C -- let me make a better record of that.
Exhibit D to your report. Is this your reliance list?
A. Yes. I provided the portion that's with my font, Garamond or ...
Q. And so beginning on page 5, was that provided by counsel for the plaintiff?
A. Yes.
Q. Do you recall reviewing the deposition of Dr. Weiss?
A. No.
Q. Did you review the deposition of David Carter?

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A. I don't recall. I don't think so.
Q. Did you ask for all of the medical records in this case?
A. Yes.
Q. Do you know if you've received all of them?
A. I mean, I didn't receive her, like, pediatric records.
I have no way of knowing if I received all of someone's medical records. I have no way of knowing that.
Q. Was there anything you requested specifically to Ms. Carter that you were not provided?
A. I don't recall requesting anything that I wasn't provided in Ms. Carter's case.
Q. Are there any other depositions relating to Ms. Carter's care that you've reviewed that are not on this list?
A. Not that I recall.
Q. What effect, if any, on your opinion that you stated earlier that the mesh deformed would the fact that the explanting physician found no roping, curling, or deformation of the mesh?
MR. CURTIS: Object to the form of the

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question.
A. I would have to see that -- where that was described and see what words were used. I can't -- I mean, I would like to see where that's described.
BY MR. SNOWDEN:
Q. Is that something that could be important for your opinion if the clinician who saw the mesh in vivo said it was not deformed?
MR. CURTIS: Object to the form of the question.
A. Well, it's somewhat subjective. I've certainly had many surgeons remove things and say, "This tumor was 4 centimeters big."
And then I get it and cut it and it's 2.5 centimeters.
So in that situation, who's right? I am.
I'm the one that cut it; I'm the one that measured it. If someone's saying -- the surgeon is saying, Well, this is -- well, okay, that's --
Okay, that's fine. It was 2.5 centimeters. I felt like it was 4.
Okay. But I measured it and it was

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2.5.
So if someone's saying, Yeah, it didn't look deformed, you'd have to ask more specific questions.
Well, was it exactly the way it was when it was put in, or do you mean it wasn't completely twisted around?
Is that what you define "deformed?"
So it's based on a particular clinician or any physician's definition of what term they're using. But I would want to see what was exactly described about it.
Because that would be -- I would think, just based on the limited amount of tissue I saw, I would be surprised that it looked normal.
BY MR. SNOWDEN:
Q. Sitting here today, you don't know one way or the other how the explanting physician testified.
A. I don't know the specific words because I already told you that I didn't review his deposition, so no.
And I don't remember there being a mention in the operative report that specifically said that it looked normal or that it wasn't

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deformed. So I don't recall that.
Q. Did the operative report mention that the mesh was deformed?
A. I don't recall. I've looked at a lot of operative reports. I'd have to rereview it.
(Exhibit 2 marked.)
BY MR. SNOWDEN:
Q. I'm handing you what's been marked Exhibit 2.
Dr. Michaels, have you reviewed this record previously?
A. Yes.
Q. And what is this record?
A. It is the pathology report from the mesh.
Q. And is this the pathology report from the hospital where the mesh was removed and then you subsequently received a portion of that?
A. Yes.
Q. Okay. Does this hospital -- well, strike that.
Let's take a look down at the gross description. It says, "Received in formalin labeled 'Carter, Tamara L, DOB 9/7/1959,' and 'mesh' are four irregular, ragged fragments of white and blue

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synthetic mesh material, with embedded tan-pink prominently congested soft tissue, that vary from 0.7-1.5 cm in greatest dimension, and are 2.3 by 2.0 by 0.8 cm in aggregate."

Do you see that?

A. Yes.

Q. It also says "representative sections of soft tissue are submitted as A1."

Do you see that?

A. Yes.

Q. So the specimen that you reviewed in this case was a portion of the whole specimen that was sent to pathology. Is that right?

A. Yes.

Q. And if we look at the diagnosis that's a couple of lines above the gross, do you see anywhere where the pathologist notes deformation of the mesh?

A. Well, deformation wouldn't be something that would be listed in the diagnosis. You wouldn't put that in the diagnosis.

If anything, it would be in the gross description, which -- in which they're described as irregular and ragged fragments of white and blue synthetic mesh.

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So actually, in fact, he is describing that these are irregular and ragged, which I would say -- a synonym of which could be "deformed," depending on how you -- depending on how you use the term "irregular and ragged."

That's certainly not normal, flattened, you know, mesh. It's clearly describing something that is deformed.

Q. And you saw representative sections of those four pieces on the -- on your slide. Right?

A. Of the pieces of tissue?

Q. Um-hmm.

A. Yes.

Q. And those pieces of tissue weren't just perfect circles or squares, they were sort of ragged fragments of tissue.

A. That's one dimension.

You know, this is different than the gross evaluation.

Q. All right. Do you see the word "deformation" on this?

A. I don't specifically see the word "deformation" on this.

Q. Okay. Do you see anything in the diagnosis

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about deformation?

A. I don't see anything in the bolded diagnosis that says anything about deformation.

Q. Anything in the bolded diagnosis or gross description about roping or curling?

A. Well, again in the gross description -- you know, you're trying to ask if they use -- if there is a very specific finding when they're using nonspecific terms.

So "irregular and ragged" could be describing something that is roped or curled. Just because they're not using the words "roped or curled," doesn't mean that they weren't.

And they are, again, not saying that these are regular, they're not saying that they're smooth. They're saying that these are irregular and ragged, so I think that actually supports the fact that this is not normal mesh.

Q. Do you see any mention on this pathology report of mesh degradation?

A. I do not see that they evaluated for mesh degradation in this report.

Q. Did they use a light microscope?

A. They did use a light microscope, but

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there's no mention of polarization microscopy.

Q. Do you need a polarized lens to assess degradation in this case?

A. You don't need a polarized lens to assess degradation, but they also did not do a microscopic description. So there's no -- we have no idea of exactly what they saw, it was just incorporated into the final diagnosis.

Q. Okay. Do you know Dr. Jonathan Strauss?

A. I know of him.

Q. Do you know where he went to medical school?

A. No.

Q. Do you know what his research interests are?

A. No.

Q. Do you know if he's avid in the field of degradation of polypropylene?

A. No.

Q. Do you know his day-to-day methods of evaluating mesh specimen?

A. No.

Q. Is there anything about -- strike that.

Does this pathology report correlate

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these findings to any of Ms. Carter's symptoms?
A. I don't understand what that question means.
Q. Looking at this pathology report, does this pathologist, Dr. Strauss, correlate his findings to Ms. Carter's symptoms?
A. I don't see any comment in this pathology report attempting to correlate these findings with Ms. Carter's symptoms.
Q. And -- because you normally wouldn't see that in a pathology report from a hospital specifically. Is that fair?
A. Well, it depends. It depends on what kind of specimen you're dealing with, and if you're asked to do that.
And in some specimens, we are asked to do that. We are asked to correlate the findings or to mention if the findings do not correlate.
And so in this particular example, he didn't say anything. So there's no mention that he was asked to or that he would feel comfortable to, or if he knew the literature with regards to mesh and complications, so no. It's just a simple pathology report.

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Q. For all you know, he could have spent the last two months doing 161 to 201 hours reviewing literature. Right?
MR. CURTIS: Object to the form of the question. This is argumentative.
A. It's pretty petty and nasty, frankly.
And I don't know anything about Dr. Strauss and what he did prior to issuing this pathology report on Ms. Carter in 2012.
BY MR. SNOWDEN:
Q. All right. Looking at the diagnosis.
Is the diagnosis found here consistent with your diagnosis?
A. I would say so.
Q. Anything different in this diagnosis from yours?
A. Well, obviously, I've expanded on mine. But I would say superficially, they're -- we found similar things with regards to what he reported.
Q. If we go to the clinical information at the top, it mentions pre-op and post-op.
Do you see that?
A. Um-hmm.
Q. And there is no indication on the pre-op or

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post-op of pain, is there?
A. I don't see anything about the word "pain" in that.
Q. And there's no mention of dyspareunia in the pre-op or post-op.
A. Not in the pre-op or post-op of the clinical information on the pathology report, that's correct.
Q. What's your understanding of why the mesh specimen you reviewed was removed from Ms. Carter?
A. Well, it looks like Dr. Weiss had noted a firm foreign body suburethrally, and then underwent an exploration for that suburethral mesh with a repair of a urethral injury, and then removed a perirectal foreign body. It was based on the erosion.
Q. Okay. Any indication to you that the mesh was removed due to pain?
A. My recollection from her deposition was that she was experiencing pain at this location.
Q. And from the medical records -- before I ask that question.
What location are you talking about?
A. The posterior vaginal wall and also, I

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think, suburethrally. Even though we don't have that specimen.
Q. Where did the specimen go that was removed suburethrally, if any?
A. I don't know what was done with it, or if it was -- what was done.
Q. You reviewed the record from September 27th, 2012?
A. I don't know what record you're talking about.
The pathology record?
Q. I'm sorry. The operative note from that date.
A. Yeah. I'd have to look at it again. I don't recall as I'm sitting here what it said.
Q. Before coming to your opinion, are you offering any opinions in this case regarding Ms. Carter's anterior vaginal wall?
A. Well, as we've already discussed, I am extrapolating the findings that I am seeing in her posterior vaginal wall from the specimen that I received. And extrapolating those findings and correlating them with her symptomatology that would have been affected by pathology of the anterior

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vaginal wall, given that the mesh has similar biologic properties and there's still mesh that's within her body.
Q. So just so I understand.
Any opinion you have on the anterior vaginal wall is not -- it's based on an extrapolation from the specimen you reviewed from the posterior vaginal wall. Do I have that right?
A. Right. Which is consistent with what we do on a day-to-day basis as pathologists where we have a small amount of tissue that's felt to be representative of a larger process. And we have opinions and form opinions and make extrapolations based on that material. That's correct.
Q. Did the treating pathologist in this case extrapolate about the anterior vaginal wall in rendering this pathologic diagnosis --
MR. CURTIS: Object --
Go ahead.
BY MR. SNOWDEN:
Q. -- about the explanted posterior mesh?
MR. CURTIS: Object to the form of the question.
A. Can you repeat that?

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MR. SNOWDEN: Can you please repeat that?
(The record was read as requested:
"Did the treating pathologist in this case extrapolate about the anterior vaginal wall in rendering this pathologic diagnosis?")
A. I don't see that he made any clinical comments on this pathology report in general.
MR. CURTIS: How much more time do you show?
MR. SNOWDEN: 16 minutes.
THE REPORTER: Would you like me to check?
MR. SNOWDEN: Sure.
MR. CURTIS: Yes.
THE REPORTER: I have 1 hour and 43 minutes on the record.
BY MR. SNOWDEN:
Q. Doctor, will you be offering any opinions at trial regarding any symptoms experienced by Ms. Carter after the mesh was removed on September 27th, 2012?
A. Well, there was only a small portion of the

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mesh removed on September 27th, so her symptoms -- let me review this.
(Document review.)
A. From my recollection, she had persistent symptoms even after the small amount of mesh was removed.
So I would say based on my findings from that particular day, knowing that there is still a significant amount of mesh material in that anatomic location, I would say that I would feel comfortable correlating her symptoms based on my examination of the mesh from this case.
BY MR. SNOWDEN:
Q. And that opinion about symptoms that postdated the September 27th, 2012, surgery that's not based on any new mesh specimen you reviewed?
A. No. I would just say that it would be -- depending on what I was asked, if she developed some sort of new complication or a different quality of a symptom, then that would obviously -- you know, I wouldn't be able to be as confident about correlating that with her current specimen that I could with the current one with the symptoms she was having prior to the surgery on September 27th, 2012.

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Q. When you were evaluating the post September 2012 symptoms, did you -- did you consider deposition testimony of Dr. -- and I'm going to butcher this name -- Tenggardjaja?
MR. SNOWDEN: I'll give you the spelling afterwards.
THE REPORTER: Thank you.
A. Well, given that I've already said that I didn't review any other deposition transcripts, I would say, no.
BY MR. SNOWDEN:
Q. Okay. On page 2 of your report under number 7, you have a statement that begins "Ms. Carter's reported signs and symptoms of exquisite pain to palpation, dyspareunia ..." and then it goes on.
Do you see that?
A. Yes.
Q. Does it matter to any of your opinions that Dr. Tenggardjaja testified that he felt Ms. Carter's pain was exaggerated?
MR. CURTIS: Object to the form of the question.
A. No.

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BY MR. SNOWDEN:
Q. Why not?
A. Because pain is subjective. And, you know, if someone under oath, or regardless, is saying that they have significant pain and there's a reason for that pain, which pathologically my opinion is that there would be a reason for that pain, whether another physician deems it to be exaggerating or not doesn't completely disqualify it.
Q. Earlier in the deposition you mentioned that there were -- I think you said tons of etiology of pain. Do you recall that?
A. Was that in this deposition?
Q. I believe so.
Anyway, are there multiple etiologies of pain?
A. Biologically, yes; and pathologically.
Q. And you would agree psychiatrically?
A. Potentially.
Q. Did you -- did you review -- well, let me start over.
Did you do a clinical differential diagnosis in this case?
A. No. I did a pathologic differential

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diagnosis.
Q. Okay. And what's the difference?
A. Well, a clinical differential diagnosis would be something that you would do clinically with a patient that presents with particular signs and symptoms.
Pathologically what I do is correlate the clinical differential diagnosis with what I'm seeing pathologically.
So I am -- I didn't examine the patient, I didn't take her history, I didn't think Oh, okay, well, her pain can be from this, from this, from this, or from this.
What I did is, I examined the pathologic specimen where a physician is taking out an area that is clearly grossly abnormal that was eroding through the vaginal wall -- you know, clearly migrated based on its location in the tissue, taking that out, submitting that to me, and my goal is to look at that and say, Okay, so what are the causes for, you know, her mesh erosion or pain, et cetera.
So mesh erosion can be because it actually didn't migrate, but that the surface of the

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mucosa ulcerated, and ulcerated down to the point of the mesh.
So it may have nothing to do with the mesh, and that's an important feature.
The patient may have had a viral infection -- herpes, CMV, any other number of viruses -- that ulcerated the mucosal surface, which then extended down into the soft tissue and then that's how the mesh was eroded.
So I look at that and say, Okay. Well, I'm looking at the mucosa, and just like Dr. Strauss did, recognize that the squamous mucosa doesn't have any significant histopathologic change, so that is not the etiology for the pain in this example.
The other thing in my differential diagnosis would be, are there any sort of neoplastic proliferations that would have grown and moved the mesh, which clearly happens.
That happens in the uterus with women that have IUDs and they have a tumor and the tumor grows and the IUD comes out. It's not because the IUD came out on its own, it's because the tumor was growing.

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So I look at the tissue, looking for any sort of tumors or neoplasms, or anything that could have grown clonally. There was nothing like that.
Look for infections other than, viruses like fungal infections. If she had been a diabetic, she may have been predisposed to fungal infections, which can be completely separate from the mesh, and that could have caused the problems that she was experiencing in that area and not from the mesh.
You can have vasculitis where the vessels become inflamed on their own and that's something that's more often in women than men.
So that would not be inconsistent with, you know, a 53-year-old woman to find vasculitis in the tissue which can cause exquisite pain.
So that's the difference between a clinical and a pathologic differential diagnosis, is that clinicians can't do that because they're not looking under the microscope. They say, Here, I'm taking this out; this is abnormal; it eroded through the mucosa, and my job is to rule out -- basically

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to evaluate why that happened.
And so that's what I did in this case and what I would do in any case, whether I specifically say it or not, in a general pathology report that I would do in a hospital. That is what is the process of reviewing all of these specimens in pathology.
Q. Is a pathologic differential diagnosis more robust than a clinical differential diagnosis?
A. I wouldn't say one is more robust than the other.
Q. Okay.
A. I would say they both have their complexities to them.
There are certainly a lot of diseases that I can diagnose under the microscope and there are certainly a lot of etiologies that a particular symptom can have. So I wouldn't say that one is necessarily more robust than the other, they're just different.
Q. Do you -- do you take into consideration the same things that a clinician would in a clinical differential diagnosis?
A. Well, only in the sense that I'm taking

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into account that this is a symptom and I'm coming up with a list of possible etiologies that I could identify histologically.
But other than that, I would say that they're different in the sense that we're evaluating different parameters.
Q. What role does the clinician's determination on reason for removal play in your pathologic differential diagnosis?
A. Well, it plays a role, because they are -- we're at their mercy for them taking out the diseased part of the tissue, or the tissue that they are concerned about.
So we have to rely on clinical differential diagnosis to then perform a good pathologic differential diagnosis. Because if she's complaining of area -- in the vaginal area -- or sorry.
If she's complaining of pain or symptomatology in the vaginal area and then they do a skin biopsy from the posterior, you know, leg, well, that's not going to really help me.
So we have to rely on one another to come to basically a consistent finding.

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Q. What pain specifically are you correlating to the specimen in this case?
A. Well, she reported pelvic pain and dyspareunia. Both. So I would say both of those would be consistent with my findings.
Q. Did you consider her prior Repliform sling with the use of bone anchors in that?
A. Yes.
Q. Did you rule it out?
A. Yes.
Q. How?
A. Because I -- from my recollection in this case from the operative report following that, they had mentioned that everything was -- it was all taken out.
And from my recollection from her deposition transcript, the quality of pain and the type of pain that she's describing is very different than any pelvic pain she had had before around the time that she initially had had that surgery.
Q. How did it change?
A. It was different type of pain.
I remember reading her deposition transcript and reading her notes and coming to the

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conclusion that it was described differently.
But I would have to, you know, go through her deposition transcript to use the exact words that she had used. I don't remember if she had said a stabbing pain or something like that, but it was described differently.
Q. Did you consider her opioid dependency in coming to your conclusions in this case?
A. Absolutely.
MR. CURTIS: Object to the form of the question.
BY MR. SNOWDEN:
Q. Did you rule those out -- rule that out?
MR. CURTIS: Object to the form of the question.
A. Well, opioid -- whether she was dependent or casual use or abuse, whatever, would not in and of itself cause a scarring and inflammatory reaction around mesh, which is what I saw.
So had she complained of pain in a vaginal area and the clinicians were pointing to it and said, "Is this painful?"
And she said "Yes, that's exquisitely painful."

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And then they took out that area and there was no mesh, no inflammation, then I would say, Hey, I don't have an explanation for it.

But in this case, that's not -- and I would say maybe it has to do with her reported use of drugs.

But in this case, that's not the case. In this case, there was mesh that was clearly described as being irregular and ragged.

Microscopically, I'm seeing scar tissue and what I'm showing on my microscopic slides is pores that have been filled with sclerotic hyalinized scar tissue, a prominent inflammatory reaction, and includes foreign-body-type giant cells, evidence of polypropylene degradation.

So these are all things that if someone was just having pain from opioid use you wouldn't see all that, you would have a biopsy and there would be nothing.

BY MR. SNOWDEN:

Q. Okay. Is that what happened during the September 27th, 2012, surgery when the physician looking for mesh in the anterior vaginal didn't find any, broke scrub, talked to the patient's husband,

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and he for the first time told the doctor that that mesh had already been removed?

MR. CURTIS: Object to the form of the question.

A. I would have to review that operative report. I don't remember that.

BY MR. SNOWDEN:

Q. You don't recall that?

MR. CURTIS: Object to the form of the question.

A. I don't remember those details.

I remember the pre-op -- I remember the pre-op diagnosis, and I remember, you know, the description of the surgery, but I don't know if it had been removed prior -- I don't know who had removed it. I don't know if they submitted it for pathology. She obviously had a lot of different clinicians that she went to, so I would have to see.

But that's not what I'm doing in this case. I'm describing what is clearly abnormal tissue.

BY MR. SNOWDEN:

Q. Was the pre-op diagnosis in this case pain?

A. No. There was no mention of pain. It just

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mentioned mesh erosion, which -- again, there's evidence that there's no other cause of this in this tissue that I examined, and female stress incontinence.

Q. Thanks, Dr. Michaels.

MR. SNOWDEN: No further questions.

MR. CURTIS: Okay.

(Proceedings concluded at 2:07 p.m.)

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

PAUL J. MICHAELS, M.D. DATE

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires:_____

_____

Notary Public

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS PRODUCTS LIABILITY LITIGATION — Master File No. 2:12-MD-02327

THIS DOCUMENT RELATES TO THE FOLLOWING CASES IN WAVE 2 OF MDL 200: — MDL 2327

JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE

Tamara Carter, et al. v. Ethicon, Inc., et al. — Civil Action No. 2:12-cv-01661

Sandra Childress, et al. v. Ethicon, Inc., et al. — Civil Action No. 2:12-cv-01564

Marion Chrysler v. Ethicon, Inc., et al. — Civil Action No. 2:12-cv-02060

Melissa Sanders, et al. v. Ethicon, Inc., et al. — Civil Action No. 2:12-cv-01562

Ana Sierra, et al. v. Ethicon, Inc., et al. — Civil Action No. 2:12-cv-01819

Toni Hernandez v. Ethicon, Inc., et al. — Civil Action No. 2:12-cv-02073

REPORTER'S CERTIFICATE
ORAL DEPOSITION OF PAUL J. MICHAELS, M.D.
June 18, 2016

I, Rebecca J. Callow, Registered Merit Reporter and Notary Public in and for the State of Texas, hereby certify to the following:

That the witness, PAUL J. MICHAELS, M.D., was duly sworn by the officer and that the transcript of the oral deposition is a true record of the testimony given by the witness;

That the original deposition was delivered to _____.

That a copy of this certificate was served on all parties and/or the witness shown herein on _____.

That pursuant to information given to the deposition officer at the time said testimony was taken, the following the amount of time used by each party at the time of the deposition:

M. Andrew Snowden (1h59m)
Attorney for Johnson & Johnson and Ethicon, Inc.

Danny L. Curtis (0h0m)
Attorney for Plaintiffs

I further certify that pursuant to FRCP Rule 30(f)(1) that the signature of the deponent:

[ ] was requested by the deponent or a party before the completion of the deposition and is to be returned within 30 days from date of receipt of the transcript. If returned, the attached Changes and Signature Page contains any changes and the reasons therefor;

[ ] was not requested by the deponent or a party before the completion of the deposition.

I further certify that I am neither counsel for, related to, nor employed by any of the parties or attorneys to the action in which this proceeding was taken. Further, I am not a relative or employee of any attorney of record in this cause, nor am I financially or otherwise interested in the outcome of the action.

SUBSCRIBED AND SWORN TO under my hand and seal of office on this the _____ day of _____, _____.

_____
Rebecca J. Callow, RMR, CRR, RPR
Notary Public, Travis County, Texas
My Commission No. 12955701-3
Expires: 09/12/2017